IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ROBERT ERDLEN, Administrator of the Estate of NATALIE N. WAIN, deceased, and GEORGE WAIN, Administrator of the Estate of SEAN M. WAIN, deceased,	)	
Plaintiffs,	)	Civil Action No.
v.	)	
PFIZER, INC.,	)	
Defendants.	)	DEMAND FOR JURY TRIAL

COMPLAINT IN CIVIL ACTION

AND NOW come the Plaintiffs, by their attorneys, Victor H. Pribanic, Esquire, and Pribanic & Pribanic, LLC, and bring this Complaint in Civil Action whereof the following is a statement:

1. The Plaintiff, Robert Erdlen, is an individual who resides at 1930 Camp Meeting Road, Sewickley, Pennsylvania 15143. He is the father of Natalie N. Wain and had been appointed the Administrator of the Estate of Natalie N. Wain by the Register of Wills of Beaver County, Pennsylvania.

2. The Plaintiff, George Wain, is an individual who resides at 107 Skrabut Lane, Sewickley, Pennsylvania 15143. He is the father of Sean M. Wain and had been appointed the Administrator of the Estate of Sean M. Wain by the Register of Wills of Beaver County, Pennsylvania.

3. Defendant Pfizer Inc. ("Pfizer" or "Defendant") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, and because there is complete diversity of citizenship between Plaintiffs and Defendant.

5. The Court has personal jurisdiction over the Defendant because the Defendant systematically and continually conducted business throughout the Commonwealth of Pennsylvania and across the United States, including marketing, advertising, and sales directed to Pennsylvania residents. Further, Defendant is present and doing business with this Commonwealth and has continuous and systematic contacts in Pennsylvania and every state in the United States of America, including the Plaintiffs' state of residence.

6. At all times relevant Defendant was engaged in the business of researching, designing, testing, developing, manufacturing, packaging, labeling, marketing, advertising, distributing, promoting, warranting and selling in interstate commerce CHANTIX, either directly or indirectly through third parties or related entities.

7. The Defendant is subject to in personam jurisdiction in the Western District of Pennsylvania because of the activity conducted therein. Defendant's activities in the Western District of Pennsylvania include: marketing, advertising, promoting, distributing, receiving substantial compensation and profits from sales and other acts that caused or contributed to the harm giving rise to this action. Defendant also made or caused to be made material omissions and misrepresentations and breaches in warranties in the Western District of Pennsylvania.

8. For purposes of remand and trial, venue is proper pursuant to 28 U.S.C. § 1391 in the United States District Court for the Western District of Pennsylvania.

9. A substantial amount of activity giving rise to the claims occurred in this District, and Defendant may be found within this District. Therefore, venue is proper in this jurisdiction under 28 U.S.C. § 1391.

10. This is an action for damages against Pfizer, Inc. The allegations, claims and theories of recovery relate to the Defendant's design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the unsafe prescription drug varenicline, which is sold by Defendant under the trade name Chantix® ("CHANTIX").

11. CHANTIX is associated with, and causes, an increased risk of serious injury and death, including: neuropsychiatric injuries leading to behavioral changes, depression, aggression, agitation, hostility, rage, suicidal ideation, suicide attempts, and, in many instances, successful suicide.

12 At all times relevant to this action, Defendant intentionally, recklessly, and/or negligently failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects, and disadvantages of CHANTIX.

13. At all times relevant to this action, Defendant intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold, and/or distributed CHANTIX as a safe prescription medication when, in fact, Defendant had reason to know, and/or did know, that CHANTIX was not safe for its intended purposes, and that CHANTIX caused serious injury and death.

14. At all times relevant to this action, Defendant is and was strictly liable for injuries caused by CHANTIX because the drug is unreasonably dangerous and is not accompanied by adequate warnings about its dangers.

15. Decedent, Sean M. Wain was prescribed and/or lawfully obtained and began using CHANTIX as indicated in October, 2007 and had been using CHANTIX for a period of one to two weeks prior to his death.

16. Decedent, Sean M. Wain used CHANTIX in a proper and reasonably foreseeable manner.

17. Decedent, Sean M. Wain, used CHANTIX in a condition that was the same or substantially similar to the same condition in which the drug was manufactured, distributed and sold.

18. Decedent, Sean M. Wain, was not aware and through diligent effort was not able to discover the risk of serious injury, rage and/or death associated with and/or caused by using CHANTIX.

19. Decedent, Sean M. Wain's healthcare providers were not aware and through diligent efforts were not able to discover the risk of serious injury, rage and/or death associated with and/or caused by CHANTIX.

20. Decedent, Sean M. Wain, would not have purchased and used CHANTIX had Defendant properly disclosed the risk of serious injury, rage, and/or death associated and/or caused by the drug.

21. At the time of ingestion, neither the drug label, packaging insert, nor the package containing the product provided adequate warnings that using CHANTIX carried a risk of experiencing serious injury, rage, and/or death as experienced by decedents.

22. Subsequent to the deaths of Natalie N. and Sean M. Wain, Defendant has issued warnings, including a black-box warning by the F.D.A. of the potential of violent behavior, rage, serious injury and death as risks associated with using the drug.

23. As a direct and proximate result of Defendant's negligence and otherwise culpable acts described herein, decedent, Sean M. Wain, consumed CHANTIX which caused decedent rage and which, in turn, resulted in violent behavior and the deaths of Sean M. Wain and Natalie N. Wain on or about May 17, 2009.

24. Decedents, Sean M. Wain and Natalie N. Wain, are survived by four minor children: Zachary Wain, Cassidy Wain, Amy Wain, and Melissa Wain.

25. As a further direct and proximate result of the negligence of Defendant and otherwise culpable acts described herein, the four surviving children of the decedents have suffered mental anguish, pain and distress, torment, suffering, and emotional distress by unexpectedly and shockingly finding their parents had been killed.

26. Plaintiffs' injuries and damages alleged more fully herein directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and/or misrepresentations.

27. Plaintiffs' injuries and damages directly resulted from using CHANTIX.

28. Defendant knew, should have known, or could have learned through reasonable diligence that CHANTIX caused and/or was associated with serious injury, violent behavior, rage, and/or death such as experienced by the decedents.

29. Upon information and belief, Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including decedents, Sean M. Wain and Natalie N. Wain, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendant and deter it from similar conduct in the future.

FACTUAL BACKGROUND

A. Design, Approval, and Promotion of CHANTIX

30. CHANTIX, known generically as varenicline, is indicated for use as an aid to quit smoking.

31. The Defendant requested and received a six-month "accelerated review" and/or "priority review" by the Federal Food and Drug Administration ("FDA") for CHANTIX. Defendant proposed the brand-name Champix for the drug, but the FDA determined that was "overly fanciful and overstates the efficacy of the product."

32. On May 2006, CHANTIX was approved for use and launched into the market for sale in the United States.

33. After gaining FDA approval, Defendant embarked upon a massive promotional campaign urging patients to use CHANTIX as a smoking cessation aid. Ian Read, Pfizer worldwide president of pharmaceutical operations, reported that the launch of CHANTIX was the biggest in Pfizer's history.[1]

34. CHANTIX became Pfizer's fastest-growing product, as major media spending on CHANTIX totaled $55 million in 2007 and nearly $60 million in the first 11 months of 2008.[2] In 2006, the year CHANTIX was launched, Pfizer reportedly spent $4.3 million in medical journal advertisements alone.[3]

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[1] *Pfizer's Lyrica Could Experience Strong Growth Going Forward*, Drug Industry Daily, Sept. 20, 2007.
[2] Shannon Pettypiece, *Pfizer Smoking Drug May Pose Suicide Risk, FDA Warns*, Bloomberg, http://www.bloomberg.com/apps/news (last visited Feb. 1, 2008); Andrew McMains, *Mcgarry Takes Pfizer's Chantix Biz*, Adweek.com, Jan. 30, 2009.
[3] Eugene May, *On the level: medical/surgical journal publishers must wait a little longer to break out from the pattern of flat revenues*, Medical Marketing & Media, April 1, 2007.

35. Consumer watchdog groups have criticized Pfizer's "sneaky" advertising of CHANTIX.[4] While most companies shrank their unbranded "education" campaign budgets as unbranded advertising declined from 2006 to 2008, Pfizer increased its "education" budget and launched unbranded advertising called My Time to Quit in December 2006.[5] The unbranded "help-seeking" advertising does not mention CHANTIX by name so it does not mention side effects associated with CHANTIX. But, it does encourage people to call a phone number of visit www.mytimetoquit.com, where they can click through to "learn about a prescription treatment option" to quit smoking – that click leads them to the CHANTIX web side.

36. Additionally, Defendant sponsored continuing medical education courses for doctors that showcase CHANTIX as a safe and effective smoking cessation medication, but course materials downplay or omit information about the serious adverse events of CHANTIX and about the types of people excluded from the clinical trials.[6] Harvard Medical school professor emeritus and former editor of the New England Journal of Medicine Dr. Arnold Relman calls this "unethical, and it is not in the public interest because it is going to bias doctors to use certain drugs."

37. Upon information and belief, Defendant similarly sponsored free smoking cessation presentations for consumers that also downplayed or omitted information about the serious adverse events of CHANTIX.

B. How it works: The Mechanism of Action

38. Nicotine in cigarettes activates 4β2 nicotinic acetylcholine subtype receptors in the brain. This triggers a large, immediate release of the neurotransmitter dopamine in the

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[4] *See e.g., Pfizer v. Chantix: Stealth advertising at its finest,* Consumer Reports Health Blog, http://blogs.consumerreports.org/health (last visited April 18, 2009).
[5] Jim Edwards, *Unbranded Ads Also Unpopular,* Brandweek.com, Sept. 29, 2008.
[6] Susanne Rust & John Fauber, *Drug firms' cash skews doctor classes* Milwaukee Journal Sentinel, Mar. 29, 2009.

brain's mesolimbic pathway, an area of the brain associated with pleasure, reward-seeking behavior, and reinforcement systems. The spike in dopamine to this "reward center" of the brain accounts for the pleasurable effects of smoking. When the dopamine levels drop after smoking a cigarette, feelings of craving and nicotine withdrawal follow.

39. CHANTIX is a selective nicotinic-acetylcholine receptor partial agonist, designed to substitute for nicotine and reduce the severity of a smoker's nicotine craving, the withdrawal symptoms from nicotine addiction and the psychological rewards with smoking.

40. CHANTIX employs a somewhat unique and/or novel mechanism of action that is intended to operate as both an "agonist" to reduce nicotine craving and withdrawal symptoms and "antagonist" to decrease nicotine craving and reduce the psychological rewards associated with smoking.[7]

41. By binding with high affinity to and partially activating the 4β2 nicotinic acetylcholine subtype receptor – the same one as nicotine activates – the drug causes a constant release of dopamine. Because CHANTIX causes the release of some dopamine, CHANTIX is intended to ease the withdrawal symptoms experienced when not smoking.[8] Because CHANTIX additionally purports to block nicotine from activating the 4β2 receptor and thus preventing the dopamine spike a smoker normally feels, CHANTIX purportedly reduced the rewarding or addictive quality of smoking.

C. Failure to adequately Study CHANTIX

42. However, Defendant negligently and/or intentionally failed to properly, fully, and/or thoroughly study, test, evaluate, and/or examine

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[7] William C. Bailey, *Pharmacologic Therapy: Novel approaches for Chronic Obstructive Pulmonary Disease*, Proc. Am. Thorac, Soc. 543-548 (2007).

[8] CHANTIX activates release of 35 to 60% of the dopamine that nicotine would have caused to flow if sitting on the exact same acetylcholine receptors. Abstract, *Varenicline: An 4β2 Nicotine Receptor Partial Agonist for Smoking Cessation*, J. Med Chem. 3474-77 (2005.

43. Defendant failed to adequately study CHANTIX to determine the risk of serious injury and/or death associated with its use, including:

a. Intentionally excluding certain patients and populations from clinical trials;

b. Intentionally ignoring any proper evaluation of depression, aggression, suicide, suicidal ideation, suicidal thoughts, suicidal tendencies, and other injuries mentioned above like diabetes, etc.;

c. Failing to determine what other effects CHANTIX has on other receptors in the human brain and body; and

d. Intentionally failing to include appropriate measures of adverse events in clinical trials.

44. For example, while studies suggest that nearly half of all cigarettes are smoked by people with mental illness,[9] Defendant admitted that "[p]atients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the controlled clinical trial program."

45. Dr. Daniel Seidman, the director of Smoking Cessation Services at Columbia University Medical Center, is reported to have said: "When they tested the drug, the sample they chose simply isn't representative of the people they're targeting. . . . By excluding drinkers, you're artificially inflating your results, potentially. I run a clinic, and two out of three [smokers] I see have a psychiatric or mood problem. None of these people would have been part of the original trials."[10]

46. Because of Defendant's systematic exclusion of patients with a history of psychiatric disorders, the safety of CHANTIX in smokers with psychiatric illness was never established. But, Defendant did not mention this in its labeling until January 2008.

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[9] Karen Lasser & J. Wesley Boyd, *Smoking and Mental Illness: a Population-based Prevalence Study*, 284 JAMA 2606-10 (2000).

[10] Derek de Koff, *This is My Brain on CHANTIX*, New York Magazine, February 10, 2008, http://nymag.com/news/features/43892.

D. CHANTIX Causes Serious Injury and Death

47. Defendant knew or should have known that CHANTIX increases the risk of causing serious injuries and death including suicide and attempted suicide and other injuries mentioned herein.

Clinical Trials Reveal Serious Risks

48. Several clinical trials demonstrate the increased risk of serious injury and death associated with CHANTIX and provided Defendant with epidemiological evidence that CHANTIX causes adverse psychiatric disorders and other injurious side effects.

49. From a 52-week, double-blind, placebo-controlled study conducted between October 2003 and March 2005, Defendant discovered that 20 out of 251 patients on CHANTIX experienced "psychiatric disorders," while only 3 patients out of 126 on a placebo experienced those disorders. The relative risk that CHANTIX patients would suffer psychiatric disorders was more than three-fold that of patients on placebo, a relative risk that was significant both clinically and statistically. This fact was not disclosed in the publication of the study, on which Kathryn Williams, then employed by Pfizer Global Research and Development, was the lead author.[11]

50. "Severe adverse events were experienced by 9.8% of the varenicline group and 7.3% of the NRT (nicotine patch) group."[12] Further, "[t]hree participants experienced serious adverse events during the non-treatment follow-up phase. . . . [One study participant] A woman in the varenicline group experienced suicidal ideation which resulted in hospitalization 11 days after completing the varenicline treatment. [She had no previously diagnosed mental and/or

[11] *See* Kathryn E. Williams et al., *A Double-Blind Study Evaluating the Long-Term Safety of Varenicline for Smoking Cessation,* 23:4 Current Med. Research and Opinions 793, 793-801 (2007).
[12] Timothy Kirn, *Varenicline may increase depression, suicide risk,* Internal Medicine News, Feb. 15, 2008.

psychological disorder.] The study investigator considered this case to be attributable to the study drug."[13]

51. On July 5, 2006, JAMA published the results of a Pfizer-sponsored study that had been completed over two years earlier in February 2004, in which one of the subjects participating in the study committed suicide.[14]

52. On July 5, 2006, JAMA also published the results of a randomized, controlled trial completed more than a year earlier in March 2005, which reported cases of serious adverse events associated with varenicline including acute psychosis, emotional liability, insomnia, and abnormal dreams.[15]

53. Defendant commissioned Dr. John Hughes to write an "independent expert opinion paper" on the association of smoking, smoking cessation, and cessation medications with suicide. Dr. Hughes reports that about one year after submitting the paper to Defendant, he converted the report into an article and submitted the article for medical journal publication in February 2008. The published article, which Dr. Hughes notes "retains significant overlap with the expert opinion paper," concluded, *inter alia*, that the three large studies of smoking abstinence found no evidence supporting the theory that stopping smoking leads to increased suicidality; that an association between Chantix and suicidality existed and required further study; and that even a small risk of suicide with smoking cessation medications "is problematic

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[13] H.J. Aubin et. al., *Varenicline versus transdermal nicotine patch for smoking cessation: results from a randomised open label trial*, 63 Thorax 717-24 (2008).
[14] S. Tonstad et al., *Effect of Maintenance Therapy With Varenicline on Smoking Cessation – A Randomized Controlled Trial*, 296 JAMA 64-71 (July 5, 2006).
[15] Jorenby et al., *Efficacy of Varenicline, an a4B2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Placebo or Sustained-Release Bupropion for Smoking Cessation – A Randomized Controlled Trial*, 296 JAMA 56-63 (July 5, 2006).

given that medications are not essential to smoking cessation, i.e., many smokers are able to quit without medication."[16]

Adverse Event and Case Reports Link CHANTIX with Serious Risks

54. Early reports of adverse events provided the Defendant with additional evidence that CHANTIX causes adverse psychiatric disorders.

55. According to a 2006 report by the European Medical Agency (EMEA), a 61-year-old man committed suicide less than a month after he finished taking CHANTIX. The EMEA's report found CHANTIX had six times the number of serious adverse reactions as the smoking cessation drug Zyban® (bupropion).

56. In the 4th quarter of 2007, varenicline accounted for 988 serious injuries in the U.S. reported to the FDA, more than any other individual drug in this time period. By comparison, the FDA received a median of 5 reports of serious injury for 769 different drugs in the 4th quarter. Only 35 drugs accounted for 100 or more reports.

57. From May 2006 through December 2007, the FDA received 227 domestic reports of suicidal acts, thoughts or behaviors, 397 cases of possible psychosis and 525 reports of hostility or aggression. These totals included 28 cases of suicide and 41 mentions of homicidal ideation, 60 cases of paranoia and 55 cases of hallucination. The categories were not mutually exclusive.

58. In November 2007, the FDA announced the results of its preliminary assessment of CHANTIX.[17] The FDA specifically highlighted the number of reports noting the association between suicide and attempted suicide "within days to weeks of initiating Chantix treatment."

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[16] John R. Hughes, *Smoking and suicide: A brief overview*, 98 Drug and Alcohol Dependence 169-178 (2008).
[17] FDA Press Release, *Early Communication About an Ongoing Safety Review: Varenicline (marketed as CHANTIX)*, http://www.fda.gov/Drug/DrugSafety/PostmarketDrugSafety (last visited March 15, 2010).

59. Many of the cases received and reviewed by the FDA were reported for patients without any prior history of psychiatric illness.

60. By July 1, 2009, the FDA reported that CHANTIX accounted for 4,762 reports of serious psychiatric events since CHANTIX's 2006 approval. Of these, 188 reported attempted suicide and 98 reported completed suicide.

61. The adverse drug event reports for varenicline describe other kinds of serious harm for which no warnings now exist. Among the most prominent are:

a. *Accidents and injuries*. A total of 173 serious events described accidental injury, including 28 road traffic accidents and 77 falls, some leading to fractures of rib, facial bones, hand, ankle, spine, and lower limbs. In these cases a variety of potential causes were identified, including loss of consciousness, mental confusion, dizziness and muscle spasms.

b. *Vision disturbances*. At least 148 reports contained medical terms indicating vision disturbances, including 68 cases described as blurred vision and 26 terms indicating transient or other forms of blindness. This reported effect could also describe a mechanism that could or did contribute to accidents and injuries.

c. *Heart rhythm disturbances*. The FDA received 224 domestic reports classified as potential cardiac rhythm disturbances. This category, however, was dominated by reports of sudden loss of consciousness, an event that could also have non-cardiac causes. However, this category also included smaller numbers of cardiac arrests and identifiable abnormal cardiac rhythms.

d. *Seizures and abnormal muscle spasms or movements*. Serious reported events included 86 cases of convulsions (seizures), 372 reports of a wide variety of movement disorders, including tremors, muscle spasms, twitching, tics, drooling, and motor hyperactivity. The extent to which these problems were resolved with a reduced dose or by halting treatment could not be determined from the data.

e. *Moderate and severe skin reactions*. Reported serious events included 338 cases of hives or swelling of the tongue, face, eyes, lips or other areas. In addition, 65 cases were classified as severe and included blisters, exfoliation of the skin and lips, and Stevens-Johnson Syndrome.

f. *Diabetes*. The FDA has received 544 reports suggesting varenicline may be related to a loss of glycemic control. This category included many

> cases of weight loss or gain that could have alternative causes, but also identified numerous cases of symptoms and laboratory tests consistent with new onset diabetes.

62. Numerous case reports have also been published in the medical literature linking CHANTIX with neuropsychiatric symptoms and behavioral changes, especially among those with some preexisting psychiatric history.[18]

63. Despite its repeated denials of a relationship between neuropsychiatric side effects including behavioral changes and CHANTIX use, described further herein, Defendant admitted to Congress in August 2008 that prior to November 20, 2007, Pfizer had actually received 322 reports of suicidal ideation, 37 reports of suicide attempt/suicidal behavior and 16 reports of a completed suicide.

E. Poor Efficacy of CHANTIX

64. Available data is inconclusive, but suggests the efficacy of CHANTIX appears to be no better than placebo or the nicotine patch.

65. Given all available data, experts remain unconvinced of relative efficacy of CHANTIX and continually express concern about the potential risks associated with using the drug.[19]

66. After reviewing three clinical trials, the experts noted: "Importantly, the majority of participants in these three studies did not quit smoking even with varenicline."[20] Additionally, the authors reviewing the studies concluded "much research needs to be conducted to establish

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[18] See e.g., Izchak Kohen & Neil Kremen, *Varenicline-Induced Manic Episode in a Patient with Bipolar Disorder*, 164:8 Am. J. Psychiatry 1269 (Aug. 2007); Robert Freedman, *Exacerbation of Schizophrenia by Varenicline*, 164:8 Am. J. Psychiatry 1269 (Aug. 2007); Anne E. Morstad, *Hypomania with Agitation Associated with Varenicline Use in Bipolar II Disorder*, 42 Annals of Pharmacotherapy, 288 (Feb. 2008); Andres Pumariega et al., *Varenicline-Induced Mixed Mood and Psychotic Episode in a Patient with a Past History of Depression*, 13:6 CNS Spectr 511 (June 2008); Michael K. Popkin, *Exacerbation of Recurrent Depression as a Result of Treatment with Varenicline*, 165:6 Am. J. Psychiatry 774 (June 2008); Fadi Alhatem & James E. Black, *Varenicline-Induced Mania in a Bipolar Patient*, 32:2 Clinical Neuropharmacology 117 (March/April 2009).

[19] *See* Kleges et al., *Varenicline for Cessation: Definite Promise But No Panacea*, 296 JAMA 94-95 (July 5, 2006).

[20] *Id.*

the effectiveness of varenicline . . . ." Although the efficacy evaluation was inconclusive, the greater risks associated with CHANTIX were clear. "First the adverse effect profile of varenicline .. . reported a rate significantly higher than with either bupropion or placebo."[21]

67. The results of a Pfizer-funded head-to-head open label trial between CHANTIX and the nicotine patch were published on February 8, 2008.[22] The results of the study demonstrated only slightly better efficacy associated with CHANTIX compared to the nicotine patch. (After 24 weeks, the efficacy for varenicline was reported to be 32.4% compared to the nicotine patch at 27.3%, but this was not considered a statistically significant difference. After 52 weeks, the efficacy for varenicline was reported to be 26.1% compared to the nicotine patch at 20.3%.)

F. Pfizer's Repeated Denials of the Risks of CHANTIX

68. Defendant has repeatedly denied the mounting scientific evidence linking CHANTIX to serious injury and death including certain psychiatric side effects and adverse events such as suicide, attempted suicide, and erratic and aggressive behavior and other injuries mentioned herein.

69. Despite its early internal knowledge that CHANTIX causes neuropsychological side effects, Defendant has diluted its label and prescribing information by minimizing and questioning the validity of post-marketing reports and epidemiological studies that reported an association between CHANTIX and neuropsychiatric and other side effects. In the Fall of 2007, for example, Pfizer representatives made the following statements:

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[21] *Id.*

[22] H.J. Aubin et. al., *Varenicline versus transdermal nicotine patch for smoking cessation: results from a randomised open label trial*, 63 Thorax 717-24 (2008).

a. Pfizer spokesman Francisco Gebauer: "[C]linical studies do not suggest a causal relationship between Chantix use and rage."[23]

b. Pfizer Vice President and Head of Global Strategy Dr. Ponni Subbiah: "To date there is no evidence to suggest that Chantix is associated with violent behavior. And I think it's important to keep in perspective that alcohol use in itself is associated with violent behavior."[24]

c. Pfizer Vice President and Head of Global Strategy Dr. Ponni Subbiah: "Our analysis to date does not suggest a causal association between Chantix and violent behavior."[25]

d. Pfizer medical director Dr. Doug Vanderburg: "Our safety data to date do not suggest a causal relationship between violent behavior and Chantix." Dr. Vanderburg reportedly acknowledged that cases of aggression and disorientation were reported during clinical trials, but said that violent tendencies may have existed in patients before they took CHANTIX.[26]

70. In a press release dated January 18, 2008, Defendant stated: "A causal relationship between Chantix and these reported symptoms has not been established. In some reports, however, an association could not be excluded."[27] But, Defendant subtly shifts blame by suggesting nicotine withdrawal caused the reported changes in behavior.[28]

71. Even after the FDA's February 1, 2008 Public Health Advisory and label change, Defendant continued to misrepresent its internal knowledge to various news agencies, like Reuters, Bloomberg, and the New Jersey Star Ledger, claiming that there is no causal relationship between CHANTIX and these behavioral changes. For example:

a. Pfizer Medical Director Dr. Anjan Chatterjee: "In the controlled clinical trial, these kinds of changes in behavior were extremely rare, occurring almost as often as the placebo. Based on the tests, we have no evidence of

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[23] Michael Gravell & Tanya Eiserer, *Girlfriend of slain musician cites anti-smoking drug*, Dallas Morning News, Sept. 5, 2007.
[24] *Girlfriend Believes Chantix Contributed to Texas Musician's Death*, ABC News, Sept. 19, 2007.
[25] On-air interview for *Chantix: Miracle Drug or Dangerous Problem?*, CBS-11/KTVT TV, Sept. 24, 2007.
[26] Sandra Osbieraj Westfall, *A New Drug for Smokers is a Dream for Some, a Nightmare for Others*, 68: No. 16 People Magazine 81, Oct. 15, 2007.
[27] "Pfizer Statement on CHANTIX (varenicline) Labeling Update in the United States," Pfizer, Inc. press release, January 18, 2008, available at http://www.pfizer.com/news/ press_releases/pfizer_ press_releases.jsp.
[28] *Id.*

any kind of consistent relationship between Chantix and aggressive behavior."[29]

72. In May 2008, the non-profit group Institute for Safe Medication Practices (ISMP) warned that CHANTIX evoked "immediate safety concerns." The ISMP analyzed the FDA's adverse event database from the fourth quarter of 2007 and found a "strong signal of multiple safety problems" with CHANTIX and a "strong signal that the risks of varenicline treatment have been underestimated."[30]

73. Pfizer responded to the May 2008 ISMP report by embarking on a massive and deceptive publicity campaign to downplay the connection between CHANTIX and neuropsychiatric and other adverse events, to question the significance of the ISMP report, and to insist that CHANTIX was properly labeled and safe for use. This organized campaign included:

a. Running advertisements in major newspapers on May 29, 2008, in which Pfizer Chief Medical Officer Joe Feczko described CHANTIX's risk-benefit profile.

b. Hosting invitation-only "roundtable" discussion events in the top five U.S. markets for select health reporters and bloggers. According to reports, at the June 5, 2008, roundtable in New York, Pfizer stressed the benefits of quitting smoking; maintained that the then-current labeling was adequate; questioned the significance of the ISMP report because the underlying data was all mostly already in the label, post-marketing reports are not the gold standard of clinical research, and the report was not published in a peer-reviewed journal; and associated smoking and/or quitting smoking with depression, irritability and suicide.[31]

c. Reviving unbranded television commercials about the importance of smoking cessation, which do not mention CHANTIX by name or CHANTIX's side effects, but which do direct people to CHANTIX as a prescription treatment for smoking cessation.

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[29] Derek de Koff, *This Is My Brain on Chantix*, N.Y. Magazine, February 18, 2008.
[30] The Institute for Safe Medication Practices, *Strong Safety Signal Seen for New Varenicline Risks*, May 2008, http://wvvw.ismp.org/docs/vareniclinestudy.asp.
[31] *See Pfizer Clears Air at Chantix Roundtable*, Wall Street Journal Health Blog, June 5, 2008, http://blogs.wsj.com/health/2008/06/05; Ed Silverman, *The Pfizer Media 'Roundtable' for Chantix*, Pharmalot.com, June 5, 2008.

d. Sending opinion pieces to newspapers to "address misperceptions and misunderstanding about the safety and efficacy of CHANTIX."[32] For example, Pfizer Chief Medical Officer Dr. Feczko authored an opinion piece in the Wall Street Journal on June 11, 2008, complaining that the media coverage of the ISMP report lacked proper context regarding smoking's dangers and detailing the limitations of the post-marketing adverse-event reporting system.

74. Sending letters to healthcare professionals about CHANTIX's risk-benefit profile.

75. Pfizer deceptively defended CHANTIX's safety profile while questioning the reliability of the May 2008 ISMP report by issuing a statement saying, in part:

> Based on Pfizer and the FDA's continuous review of all available safety information, including adverse event reports received to date, the current CHANTIX label accurately reflects the product's efficacy and safety profile. . . . We understand that the [ISMP's] report was based solely on a review of post-marketing adverse event reporting data. It is important to understand the limitations of spontaneous adverse event reporting. Often these reports lack sufficient medical information and/or have confounding factors that prevent a meaningful assessment of causality.

76. Pfizer representatives attempted to divert attention from safety issues contained in the report by discussing the benefits of quitting smoking, questioning the reliability of the report's methods, suggesting that the reported neuropsychiatric problems were caused by nicotine withdrawal or even smoking itself, and again misrepresenting its internal knowledge by insisting that the reported behavioral changes were not caused by CHANTIX and that CHANTIX was safe. For example, in May to July 2008, Pfizer representatives stated:

a. Pfizer Senior Medical Director Dr. Martina Flammer: "Chantix is a new medication that meets a huge unmet medical need. It has the highest efficacy currently available and the important thing is to put this in context."[33]

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[32] Shannon Pettypiece, *Pfizer Starts Media Ad Blitz to Address Smoking Drug Concerns*, Bloomberg, May 29, 2008 (quoting Pfizer spokesman Ray Kerins), http://www.bloomberg.com/apps/news.

[33] Shannon Pettypiece, *Pfizer's Chantix Tied to 3,000 Side Effects Reports*, Bloomberg, May 21, 2008, http://www.bloomberg.com/apps/news.

b. Pfizer's Senior Vice President for Safety and Risk Management Gretchen Dieck: "When you've got the nicotine withdrawal along with Chantix, it's just very difficult to tell what is causing it."[34]

c. Pfizer Medical Director Dr. Anjan Chatterjee: smoking "is one of the largest problems we face in the world. When you think about it in that perspective, the risk-benefit analysis is still substantially toward benefit. Even medications most people consider innocuous have side effects."[35]

d. Pfizer Senior Medical Director Dr. Martina Flammer: while patients with a history of mental illness taking Chantix should inform their doctor of their condition, "there is no indication that there is any reason why Chantix should not be taken in this population."[36]

e. Pfizer written statement: "Based on Pfizer's review of the available safety information, including certain neuropsychiatric adverse event reports received to date, we believe the Chantix label accurately reflects the product's efficacy and safety profile, thereby facilitating appropriate use by physicians and patients. It's important to note that a causal relationship between these reports and the use of Chantix has not been established."[37]

77. The "Dear Doctor" letter that Defendant sent out in May 2008 was similarly deceptive and untimely. The letter purports to provide specific guidance to physicians and patients to help mitigate the health risks of "potential" neuropsychiatric adverse events associated with CHANTIX, but still "realize the full benefits of Chantix." This letter urges doctors to continue using CHANTIX, noting that "Chantix is an important treatment option to help smokers quit, with over 5 million prescriptions written in the United State since its launch," that "smoking is the leading preventable cause of disease and premature death in the United States" and that "there are few things that provide greater health benefits than quitting smoking." This letter diluted previous information and Defendant's internal knowledge showing CHANTIX was responsible for and caused serious adverse events.

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[34] Susan Heavey, *Study sees Pfizer smoking drug risk, shares fall*, Reuters, May 21, 2008.
[35] Ricardo Alonso-Zaldivar, *FAA bans anti-smoking drug Chantix for pilots, air controllers*, LA Times, May 22, 2008.
[36] Jonathan Block (Associated Press), *Pfizer defends anti-smoking drug Chantix*, Int'l Business Times, June 5, 2008.
[37] Ed Silverman, *Widow Sues Pfizer Over Chantix Suicide*, Pharmalot.com, July 10, 2008.

78. In October 2008, after the ISMP issued another report about the continued "striking" safety signals after CHANTIX had more serious injury reports than any other prescription drugs for a second quarter, Defendant again downplayed the report and deceptively asserted a false safety profile of CHANTIX:

a. Pfizer statement: "Based on [the] totality of data, we stand by the efficacy and safety of Chantix when used as directed. Chantix labeling accurately reflects its efficacy and safety event reports and clinical trial data."[38]

b. Pfizer spokeswoman Sally Beatty: "Pfizer stands by the safety and efficacy of Chantix. There is nothing new about this data."[39]

G. Pfizer's Failure to Warn and Inadequate Warnings

79. Though Defendant knew or should have known that CHANTIX posed a risk for causing serious injury and/or death, the CHANTIX label and package insert in use when Plaintiffs' physicians prescribed the drug did not provide Plaintiffs or Plaintiffs' physicians with an adequate warning about the increased risk of serious injury and/or death from CHANTIX.

80. Pursuant to federal regulations, prescription drug labels must "contain a summary of the essential scientific information needed for safe and effective use." The label "shall be informative and accurate and neither promotional in tone nor false and misleading . . . ." *See generally* 21 C.F.R. § 201.56.

81. Specific information must go in certain label sections:

a. A *Contraindications* section "shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it . . ." 21 C.F.R. § 201.57(d).

b. A *Warnings* section "shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious

[38] Thomas H. Maugh II, *Prescription drug injuries and death reach record levels*, LA Times, Oct. 23, 2008.
[39] *Pfizer's Chantix Associated with Accidents, Suicide*, Drug Industry Daily, Oct. 24, 2008.

hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.57(e).

c. A *Precautions* section "shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug." 21 C.F.R. § 201.57(0(1).

d. An *Adverse Reactions* section would include that which "is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." 21 C.F.R. § 201.57(g). But, "any potentially fatal adverse reaction" must be contained in either the Warnings or the Contraindications section. *Id.*

82. The information contained in the CHANTIX product label and package insert in use when Plaintiffs were prescribed the drug is insufficient for many reasons, including but not limited to the following: a) the label fails to explicitly warn of increased risk for serious injury and/or death; and, b) the label fails to reference the severity and frequency of such serious injuries; and/or c) the label fails to provide adequate information advising physicians or consumers of appropriate action if certain adverse events are experienced.

83. Prior to November 20, 2007, the CHANTIX label did not adequately disclose its link with neuropsychiatric adverse effects, including but not limited to depression, agitation, hostility, rage or suicidal behavior.

84. Though FDA regulations were promulgated precisely to allow drug manufacturers to quickly strengthen label warnings with new evidence of side effects and allow Defendant to unilaterally strengthen warning labels without regulatory pre-approval pursuant to 21 CFR § 314.70(6)(iii)(A), Defendant did not change the CHANTIX label until November 2007.

85. The November 2007 label change did not adequately warn about the neuropsychiatric and other serious side effects alleged herein, and Defendant consistently minimized and diluted CHANTIX' s association with these side effects.

86. On November 20, 2007, the FDA issued an Early Communication About an Ongoing Safety Review of CHANTIX, stating that "[a] preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating Chantix treatment." While noting that smoking cessation itself is associated with nicotine withdrawal symptoms and with the exacerbation of underlying psychiatric illness, the FDA explained that not all patients with reported adverse events had pre-existing psychiatric illness and not all had discontinued smoking.[40]

87. Concurrent with the FDA Early Communication, Defendant modified the CHANTIX label and prescribing information in November 2007 by adding a short paragraph at the end of the ADVERSE REACTIONS section, on page 16 out of 22 pages, entitled "Post-Marketing Experience" that stated "depressed mood, agitation, changes in behavior, suicidal ideation and suicide" were reported as adverse reactions to CHANTIX use. The information was further diluted by a statement that "[s]moking cessation with or without treatment is associated with nicotine withdrawal symptoms and the exacerbation of underlying psychiatric illness."

88. While the November 2007 label change noted that not all patients with these reported adverse events "had known pre-existing psychiatric illness and not all had discontinued smoking," the new label also deceptively claimed that the role of CHANTIX in these reports remained unknown. The label change also added that "[p]atients should be advised to use caution driving or operating machinery until they know how quitting smoking with varenicline may affect them."

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[40] Similarly, the European Medicines Agency (EMEA) noted receiving "cases of suicidal ideation and suicide" in July, October and November 2007. The following month, the EMEA "concluded that updated warnings to doctors and patients [were necessary] to increase awareness of cases of suicidal ideation and suicide attempts" in patients using varenicline. EMEA Press Release, "European Medicines Agency concludes new advice to doctors and patients for Champix needed" (Dec. 14, 2007) at http://www.emea.europa.eu/pdfs/general/direct /pr/59551607en.pdf.

89. Defendant changed the CHANTIX label again in January 2008 to reflect what the FDA called "significant new risk information" related to CHANTIX. Again, this label change remained inadequate, and Defendant should have made it much sooner.

90. The January 2008 change added a WARNINGS section to the label, which had not previously existed, with a paragraph on "Neuropsychiatric Symptoms" that stated:

> Serious neuropsychiatric symptoms have occurred in patients being treated with Chantix. Some cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking; however, some of these symptoms have occurred in patients who continued to smoke. All patients being treated with Chantix should be observed for neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior. These symptoms, as well as worsening of pre-existing psychiatric illness, have been reported in patients attempting to quit smoking while taking Chantix in the post-marketing experience. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of Chantix and the safety and efficacy of Chantix in such patients has not been established. Patients attempting to quit smoking with Chantix and their families and caregivers should be alerted about the need to monitor for these symptoms and to report such symptoms immediately to the patient's healthcare provider.

91. The January 2008 label also added a bullet point to the Information for Patients portion of the PRECAUTIONS section of the label, which stated that:

> Patients should be informed that quitting smoking, with or without Chantix, may be associated with nicotine withdrawal symptoms (depression, agitation) or exacerbation of pre-existing psychiatric illness. Some patients have experienced depressed mood, agitation, changes in behavior, suicidal ideation and suicide when attempting to quit smoking while taking Chantix. They should be urged to report any such symptoms to their health care providers, and to reveal any history of psychiatric illness prior to initiating treatment.

92. Contemporaneous with this label change, the FDA issued a Public Health Advisory on February 1, 2008, alerting health care providers, patients, and caregivers to new

safety warnings, stating that it is "increasingly likely" that Chantix is associated with serious adverse events, including suicide."[41]

93. At a press briefing in February 2008, Dr. Bob Rappaport, the FDA's director of the Division of Anesthesia, Analgesia, and Rheumatology Products stated that: "We've become increasingly concerned as there are a number of compelling cases that truly look as if they are the result of exposure to the drug and not to other causes. We've seen cases of patients who had a history of depression, and we have seen cases of people who had no history of depression. These events are occurring sporadically, and at times in people who had no history of psychiatric disease or changes in behavior in the past."[42]

94. Relying upon newly-enacted statutory authority, in May 2008, the FDA informed Defendant that it was required to submit Risk Evaluation and Mitigation Strategies (REMS) for CHANTIX. The FDA may require REMS when it becomes aware of new safety information of which it had not been made aware at the time of approval and determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks.

95. Changes were made again to the CHANTIX label in May 2008. In the WARNINGS section, a bolded new paragraph replaced the last sentence of the previous WARNING paragraph and stated:

> Advise patients and caregivers that the patient should stop taking Chantix and contact a healthcare provider immediately if agitation, depressed mood, or changes in behavior that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.

96. In May 2008, the Information for Patients portion of the PRECAUTIONS section was also expanded, noting that patients should discontinue Chantix if certain neuropsychiatric or

[41] FDA Public Health Advisory, FDA, "Public Health Advisory—Important Information on CHANTIX (varenicline)" (February 1, 2008) at http://www.fda.gov/cder/drug/advisory/varenicline.htm.
[42] Timothy Kirn, *Varenicline may increase depression, suicide risk*, Internal Medicine News, Feb. 15, 2008.

behavioral changes occur, and that "patients should be encouraged to reveal any history of psychiatric illness prior to initiating treatment." This label change remained inadequate, and Pfizer should have made it much earlier.

97. In May 2008, the FDA also approved the addition of a Medication Guide for CHANTIX to replace the previous Patient Package Insert. This Medication Guide noted that "the most important information [patients] should know about Chantix" is that:

> Some patients have had changes in behavior, agitation, depressed mood, and suicidal thoughts or actions while using Chantix to help them quit smoking. Some people had these symptoms when they began taking Chantix, and others developed them after several weeks of treatment or after stopping Chantix. If either you, your family or caregiver notice agitation, depressed mood, or changes in behavior that are not typical for you, or if you develop suicidal thoughts or actions, stop taking Chantix and call your doctor right away.
>
> When you try to quit smoking, with or without Chantix, you may have symptoms that may be due to nicotine withdrawal, including urge to smoke, depressed mood, trouble sleeping, irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, and increased appetite or weight gain. Sometimes quitting smoking can lead to worsening of mental health problems that you already have, such as depression.
>
> Before taking Chantix, tell your doctor if you have ever had depression or other mental health problems. You should also tell your doctor about any symptoms you had during other times you tried to quit smoking, with or without Chantix.

98. The inadequate and untimely label changes of November 2007 and January 2008 did not appear in the Physician's Desk Reference (PDR) until the June 2008 "Supplement A" to the PDR was published, the inadequate and untimely label changes of May 2008 did not appear in the PDR until the 2009 update was published in about December 2008.

99. On July 1, 2009, the FDA asked Defendant to have a revised label available on its web site within 10 days that added a new BLACK BOX WARNING, the most serious warning

in the FDA's arsenal, to the CHANTIX label and that revised the WARNINGS and ADVERSE REACTIONS sections. The new black box warning, set out at the very top of the label, reads:

> WARNING:
>
> Serious neuropsychiatric events, including, but not limited to depression, suicidal ideation, suicide attempt and completed suicide have been reported in patients taking CHANTIX. Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking CHANTIX who continued to smoke.
>
> All patients being treated with CHANTIX should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide have been reported in some patients attempting to quit smoking while taking CHANTIX in the post-marketing experience. When symptoms were reported, most were during CHANTIX treatment, but some were following discontinuation of CHANTIX therapy.
>
> These events have occurred in patients with and without preexisting psychiatric disease. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of CHANTIX and the safety and efficacy of CHANTIX in such patients has not been established.
>
> **Advise patients and caregivers that the patient should stop taking CHANTIX and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.** In many post-marketing cases, resolution of symptoms after discontinuation of CHANTIX was reported, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.
>
> The risks of CHANTIX should be weighed against the benefits of its use. CHANTIX has been demonstrated to increase

> the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. The health benefits of quitting smoking are immediate and substantial.
>
> **(See WARNINGS/Neuropsychiatric Symptoms and Suicidality, PRECAUTIONS/Information for Patients, and ADVERSE REACTIONS/Post-Marketing Experience)**

100. In addition to the boxed warning, the information about driving or operating machinery in the PRECAUTIONS section was expanded to note the "post-marketing reports of traffic accidents, near-miss incidents in traffic, or other accidental injuries in patients taking CHANTIX" and that some "patients reported somnolence, dizziness, loss of consciousness or difficulty concentrating that resulted in impairment, or concern about potential impairment, in driving or operating machinery."

101. And, new information was added to the post-marketing portion of the ADVERSE REACTIONS section related to allergic reactions, such as angioedema and serious life-threatening skin reactions, like Stevens-Johnson Syndrome and Erytema Multiforme.

102. Even though this black box warning remains inadequate, given Pfizer's internal information about how CHANTIX was responsible for and cause severe adverse reactions, Pfizer should have issued this black box warning much earlier.

CAUSES OF ACTION

COUNT I:
NEGLIGENCE

103. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

104. Defendant owed Plaintiffs a duty to exercise reasonable care when designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling CHANTIX.

105. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiffs, physicians, consumers, and the public of the risks, dangers and adverse side effects of CHANTIX, including the increased risk of serious injury and death, when the drug was used as intended or in a way that Defendant could reasonably have anticipated.

106. Defendant breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of CHANTIX, as set forth below.

107. Defendant failed to exercise due care under the circumstances and therefore breached this duty in numerous ways, including the following:

a. failing to research and test CHANTIX properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of CHANTIX;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of CHANTIX which indicated serious risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of CHANTIX;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, promoting, advertising, distributing, and selling CHANTIX to physicians and consumers, including Plaintiffs, without an adequate warning of the significant and dangerous risks of CHANTIX and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting CHANTIX;

h. negligently continuing to manufacture, market, advertise, and distribute CHANTIX after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. failing to use due care in the design of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of CHANTIX;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CHANTIX, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of CHANTIX for causing serious injury and/or death in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant of the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, Plaintiffs' physicians, other consumers, the medical community, and the FDA;

n. failing to accompany CHANTIX with adequate and proper warnings regarding all possible adverse side effects, including serious injury (e.g., suicide, attempted suicide, seizure, loss of consciousness, etc.) associated with the use of the same and instructions on ways to safely use CHANTIX to avoid injury;

o. failing to use due care in the manufacture, inspection, and labeling of CHANTIX to prevent the aforementioned risk of injuries to individuals who used the drug;

p. failing to use due care in the promotion of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. failing to use due care in the sale and marketing of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. failing to use due care in the selling of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of CHANTIX;

u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and

death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;

v. failing to educate healthcare providers, patients, and the public about the safest use of the drug;

w. failing to give patients and healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

x. being otherwise reckless, careless and/or negligent.

108. Despite the fact that Defendant knew or should have known that CHANTIX increased the risk of serious injury and/or death, Defendant continued to promote and market CHANTIX to doctors and to consumers, including Plaintiffs, when safer and more effective methods of treatment were available.

109. As a direct and proximate consequence of Defendant's negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiffs sustained injuries and damages including severe and permanent physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

110. **WHEREFORE**, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II:
NEGLIGENCE PER SE
(Violation of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)

111. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

112. At all times herein mentioned, Defendant had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of CHANTIX.

113. By reason of its conduct as alleged herein, Defendant violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding CHANTIX;

b. Defendant failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

c. Defendant failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57; and

d. Defendant advertised and promoted CHANTIX in violation of 21 C.F.R. § 202.1; and

e. Defendant violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the CHANTIX label to reflect the evidence of an association between CHANTIX and the serious neuropsychiatric and physical adverse events suffered by Plaintiff.

These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiffs. Defendant's violations of these statutes and regulations constitute negligence per se.

114. As a direct and proximate result of Defendant's statutory and regulatory violations, Plaintiffs, members of the class of persons protected by the above-mentioned statutes, suffered, and will continue to suffer, injuries and are entitled to compensatory damages, and

exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proved at trial.

115. **WHEREFORE**, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III:
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

116. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

117. Defendant has a duty to provide adequate warnings and instructions for CHANTIX, to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately test its product.

118. At all times relevant to this action, the Defendant researched, designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold CHANTIX, placing the drug into the stream of commerce.

119. At all times relevant to this action, CHANTIX was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was defective and unreasonably dangerous to consumers, including the Plaintiffs.

120. CHANTIX is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

121. CHANTIX was expected to reach, and did reach, users and/or consumers, including Plaintiffs, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

122. Sean M. Wain, deceased, used CHANTIX as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

123. CHANTIX was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiffs, including when it was used as intended and in a reasonably foreseeable manner.

124. CHANTIX was unreasonably dangerous and defective in design or formulation for its intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk of serious neuropsychiatric and other serious injury which could have been reduced or avoided, *inter alia*, by the adoption of a feasible reasonable alternative design. There were safer alternative methods and designs for the like product.

125. CHANTIX was insufficiently tested and caused harmful side effects that outweighed any potential utility.

126. CHANTIX, as manufactured and supplied, was defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

127. CHANTIX as manufactured and supplied by the Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of injuries from use and/or ingestion and acquired additional knowledge and information confirming the defective and dangerous nature of CHANTIX, Defendant failed to provide adequate warnings to the medical community and the consumers, to whom Defendant

was directly marketing and advertising; and, further, Defendant continued to affirmatively promote CHANTIX as safe and effective. Even when Defendant issued label changes, it immediately diluted those changes in its publicity campaigns set forth above.

128. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that CHANTIX should not have been marketed in that condition.

129. As a direct and proximate cause of the Defendant's defective design of CHANTIX, including the lack of appropriate warnings, Plaintiffs were prescribed and used the drug rather than less expensive alternative smoking cessation therapies with better and/or similar efficacy. As a result, Plaintiffs suffered the damages and injuries described herein, including severe and permanent physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

130. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of the defective design of the dangerous drug.

131. **WHEREFORE**, Plaintiffs demand judgment against Defendant and seek damages: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV:
STRICT PRODUCTS LIABILITY — FAILURE TO WARN

132. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

133. CHANTIX was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert consumers, including

Plaintiff's decedent, of the dangerous risks and reactions associated with the subject product, including but not limited to the risk of serious injury and/or death, including but not limited to suicidal ideation, attempted suicide and suicide and other injuries mentioned herein like diabetes, etc.

134. Information given by Defendant to the medical community and to consumers concerning the safety and efficacy of CHANTIX, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects.

135. Had adequate warnings and instructions been provided, Plaintiff's decedent would not have been prescribed or taken CHANTIX, and would not have been at risk of the harmful side effects described herein.

136. Neither Plaintiff's decedent, nor Plaintiff's decedent's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by CHANTIX.

137. Defendant knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by CHANTIX.

138. Plaintiff's decedent, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendant.

139. Defendant expected Plaintiff's decedent, individually and through his prescribing physicians, to rely upon the information contained in the subject product's package insert and other advertising and promotional materials.

140. Defendant had a continuing duty to warn Plaintiff's decedent and his prescribing physicians of the dangers associated with the subject product.

141. Safer alternatives were available that were just as effective and without the risks posed by CHANTIX.

142. As a direct and proximate consequence of the defective nature of CHANTIX and the Defendant's failure to provide adequate warnings about the dangers associated with the drug, the Plaintiffs sustained injuries and damages alleged herein including severe and permanent physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

143. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its failure to warn and/or adequately warn the Plaintiff's decedent and healthcare professionals about the increased risks of serious injury and death caused by Chantix.

144. **WHEREFORE**, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V:
BREACH OF EXPRESS WARRANTY

145. Plaintiffs repeat and re-allege each and every allegation of Master Complaint as if set forth in full in this cause of action.

146. Defendant expressly represented to Plaintiff's decedent (and to other consumers and the medical community) that CHANTIX was safe, well-tolerated, efficacious and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

147. Defendant breached expressed warranties with respect to CHANTIX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX;

b. Defendant represented that CHANTIX was as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that CHANTIX was not safer than alternatives available on the market; and

c. Defendant represented that CHANTIX was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.

148. CHANTIX does not conform to Defendant's express representations because it is not safe or well-tolerated since it has numerous and serious unwarned-of side effects, causes severe and permanent injuries and was not adequately tested, and it is not much more, if at all, efficacious than alternative smoking cessation treatments and methods.

149. At all relevant times, CHANTIX did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

150. Plaintiff's decedent, Plaintiff's decedent's physicians, other consumers, and the medical community relied upon Defendant's express warranties, resulting in Plaintiff's decedent's ingestion of the drug.

151. As a direct and proximate consequence of Defendant's breach of its warranties, the Plaintiffs sustained injuries and damages alleged herein including severe and permanent physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

152. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its breach of warranty.

153. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other further relief as this Court deems just and proper.

COUNT VI:
BREACH OF IMPLIED WARRANTY

154. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

155. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold CHANTIX.

156. At all relevant times, Defendant intended that CHANTIX be used in the manner that Plaintiff's decedent in fact used it.

157. Defendant impliedly warranted CHANTIX to be of merchantable quality, safe and fit for the use for which Defendant intended it, and Plaintiff's decedent in fact used it.

158. Defendant was aware that consumers, including Plaintiff's decedent, would use CHANTIX as an aid to quit smoking; which is to say that Plaintiff's decedent was a foreseeable user of Defendant's product CHANTIX.

159. Defendant knew, or had reason to know that Plaintiff's decedent's physicians would rely on Defendant's judgment and skill in providing CHANTIX for its intended use.

160. Plaintiff's decedent and his physicians reasonably relied upon the skill and judgment of Defendant as to whether CHANTIX was of merchantable quality, safe and fit for its intended use.

161. The drug was expected to reach and did in fact reach consumers, including Plaintiff's decedent, without substantial change in the condition in which it was manufactured and sold by Defendant.

162. Defendant breach various implied warranties with respect to CHANTIX including the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX;

b. Defendant represented that CHANTIX was as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that CHANTIX was not safer than alternatives available on the market; and

c. Defendant represented that CHANTIX was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.

163. In reliance upon Defendant's implied warranty, Plaintiff's decedent used CHANTIX as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

164. Defendant breached its implied warranty to Plaintiff's decedent in that CHANTIX is unreasonably dangerous, defective, and unfit for the ordinary purposes for which CHANTIX was used. It was not of merchantable quality, safe and fit for its intended use, or adequately tested.

165. Defendant breached the implied warranty that CHANTIX was of merchantable quality and fit for such use in violation of 13 Pa. Stat. Ann. §2314 *et seq.*

166. As a direct and proximate consequence of Defendant's breach of its warranty, the Plaintiffs sustained injuries and damages alleged herein including severe and permanent physical

injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

167. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its breach of implied warranty.

168. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT VII:
FRAUDULENT MISREPRESENTATION AND CONCEALMENT

169. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

170. Defendant intentionally and fraudulently misrepresented to consumers and physicians, including Plaintiff's decedent, Plaintiff's decedent's physicians and the public in general, that CHANTIX had been tested and found to be safe, well-tolerated and/or more efficacious than alternative medications and/or methods of smoking cessation and that CHANTIX's benefits outweighed its risks when used as instructed, when, in fact, Defendant knew, or should have known, and fraudulently concealed that CHANTIX is dangerous to the well-being of patients and that the benefits of its use are far outweighed by the risks for Plaintiffs and many others.

171. At all relevant times, Defendant knew of the use for which CHANTIX was intended and expressly and/or impliedly warranted its drug was of merchantable quality and safe and fit for such use.

172. Defendant had sole access to material facts concerning the dangers and unreasonable risks of CHANTIX.

173. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of CHANTIX and its intentional dissemination of promotional and marketing information about CHANTIX for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the drug.

174. Defendant made false affirmative representations, omissions, and/or fraudulently concealed material adverse information regarding the dangers, risks, safety, benefits, utility and effectiveness of CHANTIX in order to induce Plaintiff's decedent, Plaintiff's decedent's physicians, and the public in general to rely upon such representations and to use CHANTIX. By failing to disclose important safety and injury information and suppressing material facts about CHANTIX to Plaintiff's decedent, Plaintiff's decedent's physicians, and the public in general, Defendant further led Plaintiff's decedent and Plaintiff's decedent's physicians to rely upon the safety of CHANTIX.

175. Defendant had a duty to disclose such information, arising from Defendant's actions or making, marketing, promoting, labeling, distributing and selling pharmaceutical products to Plaintiff's decedent and others.

176. Defendant's false representations and concealments were fraudulently made, in that CHANTIX in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

177. Defendant committed acts of intentional misrepresentation and intentional concealment by suppressing material facts relating to the dangers and substantial risks of serious injuries and/or death associated with, and caused by, the use of CHANTIX.

178. Defendant made such false representations, omissions and concealments with the intent or purpose that Plaintiff's decedent and Plaintiff's decedent's physicians would rely upon representations, leading to the use of CHANTIX by Plaintiff's decedent.

179. Defendant made fraudulent affirmative misrepresentations and omissions and fraudulent concealments of material facts regarding the safety and effectiveness of CHANTIX and of the dangers and risks of injuries associated with CHANTIX, including:

a. Defendant fraudulently represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX had been adequately tested and found to be safe and effective as an aid to smoking cessation, and fraudulently concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX; and

b. Defendant fraudulently represented that CHANTIX was as safe and/or safer and/or more efficacious than other alternative smoking cessation therapies, and fraudulently concealed information that demonstrated that CHANTIX was not safer and/or more efficacious than alternative available on the market.

180. Defendant knew, or reason to know, or should have known that these representations and actively concealing adverse information were false, and that CHANTIX had defects and was unreasonably dangerous. Yet, Defendant willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of CHANTIX to consumers, including Plaintiffs, and to the medical community.

181. Defendant did not have adequate proof upon which to base such representations, and in fact, given Defendant's knowledge about CHANTIX's pharmacology and reported adverse events, Defendant knew or should have known that these representations, omissions

and/or concealments were false and fraudulent. Specifically, Defendant knew of, possessed evidence and/or had reason to know that CHANTIX had defects and was unreasonably dangerous, causing neuropsychiatric side effects, including but not limited to depression, agitation, hostility, rage and suicidal thoughts and actions, as detailed herein.

182. Defendant's misrepresentations were made with the intent that physicians and patients, including Plaintiff's decedent, would rely upon them and were made with the intent of defrauding and deceiving Plaintiff's decedent, other consumers, and the medical community to induce and encourage the sale of CHANTIX.

183. Plaintiff's decedent, Plaintiff's decedent's physicians, and others, did rely upon and/or were induced by the misrepresentations, omissions and/or active concealment of the dangers of CHANTIX to the detriment of the Plaintiffs.

184. Defendant's fraudulent representations and concealments evince its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff's decedent.

185. In selecting treatment, Plaintiff's decedent's physicians and Plaintiff's decedent relied on and were induced by Defendant's misrepresentations concerning the dangers of CHANTIX.

186. As detailed herein, Defendant made these fraudulent misrepresentations, omissions and concealments through statements and comments to the press, labeling, advertising, marketing and promotion materials, detailers, seminar presentations, publications, Dear Doctor letters and regulatory submissions.

187. Defendant's fraudulent conduct also included manipulating the medical literature. Defendant shaped the medical literature about CHANTIX, such that the literature cannot

accurately reflect CHANTIX's dangers. Defendant wrongfully portrayed these conclusions as objective scientific conclusions by medical scientists. For example, the Pfizer-employee-authored report of a pre-clinical study discussed above did not disclose that CHANTIX users suffered psychiatric disorders more than placebo users at a statistically and clinically significant rate.

188. Plaintiffs and the treating medical community did not know that the representations, omissions, and/or concealments made by Defendant were false and were justified in reasonably relying upon Defendant's representations.

189. Had Defendant not fraudulently misrepresented and concealed such information, Plaintiff's decedent would not have ingested CHANTIX and suffered resulting harm.

190. Defendant made the aforesaid representations and concealments intentionally and in the course of Defendant's business as designers, manufacturers, and distributors of CHANTIX despite having no reasonable basis for the assertion that these representations were true, without having accurate or sufficient information concerning the aforesaid representations and/or knowing these representations were false. Defendant was aware that without such information it could not accurately make the aforesaid representations.

191. At the time Defendant made the aforesaid representations and at the time Plaintiff's decedent received CHANTIX, Plaintiff's decedent, Plaintiff's decedent's physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff's decedent received CHANTIX, Defendant failed to adequately inform Plaintiff's decedent and/or his prescribing doctors that CHANTIX caused neuropsychiatric side effects, including but not limited to depression, agitation, hostility, rage and suicidal thoughts and actions, despite Defendant being in possession of such evidence. Plaintiff's decedent received no adequate

warnings, either written or verbal, that CHANTIX caused these side effects, and Plaintiff's decedent relied on these omissions and concealments.

192. CHANTIX's label changes detailed herein should have come sooner and/or were fraudulent and misleading because they downplayed any association and causal relationship, in spite of Defendant's awareness of causation.

193. As a direct and proximate consequence of Defendant's fraudulent misrepresentations, omissions and intentional concealment of material facts, upon which Plaintiff's decedent reasonably relied, Plaintiffs sustained injuries and damages alleged herein including severe and permanent physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

194. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its fraudulent misrepresentations, omissions and concealments.

195. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT VIII:
NEGLIGENT MISREPRESENTATION AND CONCEALMENT

196. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

197. At all relevant times, Defendant designed, tested, manufactured, packaged, marketed, distributed, promoted and sold CHANTIX.

198. At all relevant times, Defendant knew of the use for which CHANTIX was intended and expressly and/or impliedly warranted that the drug was of merchantable quality and safe and fit for such use.

199. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of CHANTIX and its intentional dissemination of promotional and marketing information about CHANTIX for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the drug.

200. Defendant recklessly and/or negligently represented to Plaintiff's decedent, Plaintiff's decedent's physicians, and other persons and professionals on whom it was known by Defendant that they would rely, that CHANTIX was safe to ingest and that the utility of this product outweighed any risk in use for their intended purposes.

201. Defendant recklessly and/or negligently failed to disclose to Plaintiff's decedent, and others, important safety and efficacy information, thereby suppressing material facts about the drug, while having a duty to disclose such information, which duty arose from its actions of making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff's decedent and others.

202. Defendant led Plaintiff's decedent to rely upon the safety of the product in its use.

203. The false representations of the Defendant were reckless and/or negligently made in that CHANTIX in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

204. Defendant committed acts of reckless and/or negligent misrepresentation and reckless and/or negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of CHANTIX.

205. Defendant knew of should have known that its representations and/or omissions were false. Defendant made such false, negligent and/or reckless representations with the intent or purpose that Plaintiff's decedent and Plaintiff's decedent's physicians would rely upon such representations, leading to the use of CHANTIX by Plaintiff's decedent.

206. Defendant, recklessly and/or negligently misrepresented and/or omitted information with respect to CHANTIX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX;

b. Defendant represented that CHANTIX was as safe and/or safer than other alternative smoking cessation therapies and fraudulently concealed information that demonstrated that CHANTIX was not safer than alternatives available on the market; and

c. Defendant represented that CHANTIX was more efficacious than other alternative smoking cessation therapies and fraudulently concealed information regarding the true efficacy of the drug.

207. Defendant made affirmative misrepresentations and recklessly and/or negligently omitted material adverse information regarding the safety and effectiveness of CHANTIX.

208. Defendant made these misrepresentations and/or omissions at a time when Defendant knew or had reason to know that CHANTIX had defects and was unreasonably dangerous and was not what Defendant had represented to the medical and healthcare community, the FDA, and the consuming public, including Plaintiffs.

209. Defendant omitted, suppressed, and/or concealed material facts concerning the dangers and risk of injuries associated with the use of CHANTIX, including serious injury and death. Furthermore, Defendant's purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of CHANTIX in order to increase sales.

210. Defendant's misrepresentations and/or omissions were undertaken by Defendant with an intent that doctors and patients, including Plaintiff's decedent, rely upon them.

211. Defendant's misrepresentations and/or omissions were undertaken with the intent of defrauding and/or deceiving Plaintiff's decedent, other consumers, and the medical community to induce and encourage the sale of CHANTIX.

212. Defendant's misrepresentations and/or omissions evinced the Defendant's callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff's decedent.

213. Plaintiff's decedent's physicians and Plaintiff's decedent relied on and were induced by Defendant's misrepresentations, omissions, and/or active concealment of the dangers of CHANTIX in selecting treatment.

214. Plaintiff's decedent and Plaintiff's decedent's physicians did not know that the representations made by Defendant were false and were justified in relying upon Defendant's representations.

215. Had Plaintiff's decedent been aware of the increased risk of side effects associated with CHANTIX and the relative efficacy of CHANTIX compared with other readily available alternative smoking cessation therapies, Plaintiff's decedent would not have taken CHANTIX.

216. As a direct and proximate consequence of Defendant's misrepresentations, Plaintiffs sustained injuries and damages alleged herein including severe physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

217. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its negligent misrepresentations, omissions, and concealment.

218. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT IX:
GROSS NEGLIGENCE

219. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

220. Defendant had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of CHANTIX, including a duty to ensure that it did not cause users to suffer from unreasonable and dangerous side effects.

221. Defendant failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product, CHANTIX, in that Defendant knew or should have known that taking CHANTIX caused unreasonable and life-threatening injuries, as alleged herein.

222. Defendant was grossly negligent under the circumstances and breached its duty of care in numerous ways, including the following:

a. failing to test CHANTIX properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of CHANTIX;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post- marketing tests of CHANTIX which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of CHANTIX;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling CHANTIX to consumer, including Plaintiffs, without an adequate warning of the significant and dangerous risks of CHANTIX and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting CHANTIX;

h. recklessly continuing to manufacture, market, advertise, and distribute CHANTIX after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. failing to use due care in the design of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of CHANTIX;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CHANTIX, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of CHANTIX for causing serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately, and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and

testing to Plaintiffs, their doctors, other consumers, the medical community, and the FDA;

n. failing to accompany CHANTIX with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and labeling of CHANTIX to prevent the aforementioned risk of injuries to individuals who used the drug;

p. failing to use due care in the promotion of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. failing to use due care in the sale and marketing of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. failing to use due care in the selling of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

s. failing to provide adequate and accurate training and information to the sale representatives who sold the drug;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of CHANTIX;

u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing such serious injury and death, as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;

v. failing to educate healthcare providers, patients, and the public about the safest use of the drug;

w. failing to give healthcare providers adequate information to weight the risks of serious injury and/or death for a given patient; and

x. being otherwise grossly negligent.

223. Although Defendant knew, or recklessly disregarded, the fact that Defendant's product, CHANTIX, caused potentially lethal side effects, Defendant continued to market

Defendant's product, CHANTIX, to consumers, including Plaintiffs, without disclosing these side effect, including the risks of serious injury and/or death.

224. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiffs would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

225. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product, CHANTIX, as set forth herein, but continued to design, manufacture, market, and sell Defendant's product, CHANTIX, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious and/or reckless disregard of the foreseeable harm caused by Defendant's product, CHANTIX.

226. As a direct and proximate consequence of Defendant's gross negligence, the Plaintiffs sustained injuries and damages alleged herein including severe physical injuries and/or death, severe emotional distress, economic losses and other damages to be proved at trial.

227. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its gross negligence.

228. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT X:
UNJUST ENRICHMENT

229. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

230. At all times relevant to this action, Defendant designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold CHANTIX.

231. Plaintiff's decedent purchased CHANTIX for the purpose of stopping smoking.

232. Defendant has accepted payment from Plaintiff's decedent for the purchase of CHANTIX.

233. Plaintiff's decedent did not receive the safe and effective pharmaceutical product for which Plaintiffs intended to purchase.

234. It is inequitable and unjust for Defendant to retain this money because the Plaintiff's decedent did not in fact receive the product Defendant represented CHANTIX to be.

235. By reason of the foregoing, Plaintiffs are entitled to equitable relief against Defendant on account of its unjust enrichment.

236. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT XI:
PUNITIVE DAMAGES

237. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

238. At all times material hereto, Defendant knew or should have known that CHANTIX was inherently more dangerous than other methods of smoking cessation with respect to the risks included, but not limited to, the risks of serious injury, agitation, extreme changes in mood and behavior, vivid or unusual dreams, aggression, depression, permanent psychological

damages, chest palpitations, diabetes, suicidal and homicidal thoughts and actions, and suicide risks that exceed the benefits of CHANTIX.

239. At all times material hereto, Defendant attempted to and did misrepresent, conceal, and omit facts concerning the safety of CHANTIX, as detailed herein.

240. At all times material hereto, the Defendant knew and recklessly disregarded the fact that CHANTIX causes debilitating and potentially lethal side effect with greater frequency than safer alternative methods of smoking cessation.

241. Notwithstanding the foregoing, Defendant continued to aggressively market the subject product to consumers, including Plaintiff's decedent, without disclosing the side effects, when there were safer alternative methods of smoking cessation.

242. Defendant knew of CHANTIX's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff's decedent, in conscious and/or negligent disregard of the foreseeable harm caused by CHANTIX.

243. Defendant intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff's decedent, the potentially life threatening side effects of CHANTIX in order to ensure continued and increased sales.

244. The Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff's decedent of necessary information to enable Plaintiff's decedent and his physicians to weigh the true risks of using the CHANTIX against its benefits.

245. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff's decedent, Plaintiffs have

suffered and will continue to suffer severe and permanent physical injuries. Plaintiffs have endured substantial pain and suffering and has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiffs' injuries and damages are permanent and will continue into the future.

246. Defendant's conduct detailed herein was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff's decedent, thereby entitling each Plaintiff to punitive damages in an amount appropriate to punish the Defendant and to deter them from similar conduct in the future.

247. By reason of the foregoing, Plaintiffs are entitled to punitive damages.

248. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT XII:
VIOLATIONS OF PENNSYLVANIA STATE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR AND DECEPTIVE TRADE PRACTICES

249. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

250. Defendant had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of CHANTIX to Plaintiffs.

251. Defendant engaged in unfair, unconscionable, deceptive fraudulent and misleading acts or practices in violation of all states' consumer protection laws, identified below.

252. Through its false, untrue and misleading promotion of CHANTIX, Defendant induced Plaintiff's decedent to purchase and/or pay for the purchase of CHANTIX.

253. Defendant misrepresented the alleged benefits and characteristics of CHANTIX; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of CHANTIX; misrepresented the quality and efficacy of CHANTIX as compared to much lower-cost alternatives; misrepresented and advertised that CHANTIX was of a particular standard quality, or grade that it was not; misrepresented CHANTIX in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff's decedent would have switched from CHANTIX to another smoking cessation option and/or chosen not to purchase and/or reimburse for purchases of CHANTIX; advertised CHANTIX with the intent not to see it as advertised; and otherwise engaged in fraudulent and deceptive conduct.

254. Defendant's conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendant's conduct misled, deceived and damaged Plaintiffs, and Defendant's fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiff's decedent rely on said conduct by purchasing and/or paying for purchases of CHANTIX. Moreover, Defendant knowingly took advantage of Plaintiff's decedent, who was reasonably unable to protect his interests due to ignorance of the harmful adverse effects of CHANTIX.

255. Defendant's conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiffs and offends the public conscience.

256. Plaintiff's decedent purchased CHANTIX primarily for personal and family purposes.

257. As a result of Defendant's violative conduct, Plaintiff's decedent purchased and/or paid for purchases of CHANTIX that were not made for resale.

258. Defendant engaged in unfair competition or deceptive acts or practices in violation of 73 Pa. Stat. § 201.1, *et seq.*

259. As a proximate result of Defendant's misrepresentations and omissions, Plaintiffs have suffered ascertainable losses, in an amount to be determined at trial.

260. By reason of the foregoing, Defendant is liable to Plaintiffs for damages as a result of its violations of applicable state law prohibiting consumer fraud and deceptive and unfair trade practices.

261. WHEREFORE, Plaintiffs demand judgment against Defendant and seek damages including: compensatory damages, exemplary damages and punitive damages, together with interest, the costs of suit and attorney's fees, and such other and further relief as this Court deems just and proper.

COUNT XIII:
WRONGFUL DEATH

262. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

263. Natalie Wain and Sean Wain, deceased, died as a direct and proximate result of Defendant's misconduct as alleged herein resulting in Decedent's use of CHANTIX and are survived by the aforenamed family members.

264. As a direct and proximate result of the acs and/or omission of Defendant, Decedents' heirs and family have been deprived of their future aid, income, assistance, services, companionship, society, affection and financial support.

265. The representatives or administrators of Plaintiffs' Decedents' estates bring these claims on behalf of the Plaintiffs' Decedent's lawful heirs for Decedents' wrongful death.

266. Plaintiffs' Decedents' estate representatives bring these claims on behalf of Plaintiffs' Decedents' lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

267. Plaintiffs' Decedents' estate representatives further plead all wrongful death damages allowed by statute and law in the Commonwealth of Pennsylvania.

COUNT IX: SURVIVAL

268. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

269. As a direct and proximate result of Defendant's misconduct as alleged herein, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disfigurement, mental anguish, loss of enjoyment of life, medical expenses, loss of earnings and loss of earning capacity prior to Plaintiffs' Decedents' deaths.

270. The representatives or administrators of Plaintiffs' Decedents' estates bring these claims on behalf of Plaintiffs' Decedents' estates and Plaintiffs' Decedents' beneficiaries for damages.

271. The Administrators of Decedent Plaintiffs' estates are entitled to recover damages, to which Decedent Plaintiffs would have been entitled and further plead all survival damages allowed by statute and law in the Commonwealth of Pennsylvania.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant as follows:

A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress;

past and future loss of enjoyment of life; past and future lost wages and loss of earning capacity; funeral and burial expenses; and consequential damages;

B. Punitive damages in an amount sufficient to punish Defendant and set an example;

C. Disgorgement of profits;

D. Restitution;

E. Costs and fees of this action, including reasonable attorney's fees;

F. Prejudgment interest and all other interest recoverable; and

G. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

TOLLING OF THE LIMITATIONS PERIOD

272. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff's decedent and Plaintiff's decedent's healthcare providers the true and significant risks associated with taking CHANTIX.

273. As a result of Defendant's actions, Plaintiff's decedent and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff's decedent has been exposed to the risks identified in this Complaint, and that those risks were the result of Defendant's acts, omissions, and misrepresentations.

274. Accordingly, no limitations period ought to accrue until such time as Plaintiffs knew or reasonably should have known of some causal connection between Plaintiff's decedent's ingestion of CHANTIX and the harm Plaintiffs suffered as a result.

275. Additionally, the accrual and running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

276. Additionally, Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described.

277. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

Respectfully submitted this 6 day of May, 2011.

PRIBANIC & PRIBANIC

By _____
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